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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,958	03/26/2004	Christopher P. Henderson	59698US002	9828

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EXAMINER

PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3772

NOTIFICATION DATE	DELIVERY MODE
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12/12/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/810,958

Applicant(s)

HENDERSON ET AL.

Examiner

Nihir Patel

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09.27.2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on September 27th, 2007 have been fully considered but they are not persuasive. In reference to the applicant's arguments that the objection of the specification under 35 USC 132(a) cannot be sustained, the examiner disagrees.

In the original specification the applicant defines a mask body as:

means a structural member that is configured to fit over a person's nose and mouth and that helps define an interior gas space separate from an exterior gas space.

In the original specification the applicant defines a rigid insert as:

a relatively stiff structural member that has been used on respiratory masks to provide adequate structure for attaching fluid communication components such as filter cartridges and exhalation valves while being joined to a more compliant portion that makes contact with and generally conforms to a wearer's face.

In the amended specification the applicant defines a mask body as:

means **the parts of a respiratory mask that extends in spaced relation away from a wearer's face during use and over their** nose and mouth to help define an interior gas space that is separate from an exterior space.

The bolded part indicated above defines the new matter in the definition of a mask body.

In the amended specification the applicant defines a rigid insert as:

a relatively stiff structural member that has been used on respiratory masks to provide adequate structure for attaching fluid communication components such as filter cartridges and exhaust valves while being joined to a more compliant **mask body port** that makes contact with and generally conforms to a wearer's face.

The bolded part indicated above defines the new matter in the definition of a rigid insert.

Applicant also argues that there is no indication that Nelson's hard shell would be able to be deformed such that the first and second cheek portions of the mask body can move towards each other about an axis when the mask is held stationary and a force is exerted on the nose and chin portion. The examiner disagrees. See figures 6 and 7; inherently when the mask is used as shown in figure 7 the mask body can move towards each other about an axis when the mask is held stationary and a force is exerted on the nose and chin portion.

Specification

2. The amendment filed on May 29th, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "The part of a respiratory mask that extends in space relation away from a wearer's face during use and over their nose and mouth to help define an interior gas space that is separate from an exterior gas space" and "Rigid insert refers to a relatively stiff structural member that has been used on respiratory masks to provide adequate structure for attaching fluid communication components such as filter cartridge and exhalation

valves while being joined to a more compliant mask body part that makes contact with and generally conforms to a wearer's face".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims **1-3, 5, 8, 29 and 32** are rejected under 35 U.S.C. 102(b) as being anticipated by Neslon et al. (Us 4,960,121).

5. **As to claims 1 and 32**, Nelson teaches a half-face mask assembly that comprises a mask body 12 (see **figures 1-3 and column 2 lines 20-30**) that lacks a rigid insert that is non-elastomeric (see **column 2 lines 35-40**), and that is adapted for fitting over a person's nose and mouth, the mask body having a nose portion, a chin portion, first and second cheek portions, and an axis that extends from the nose portion to the chin portion (see **figures 6 and 7**), the mask body being constructed to deform such that the first and second cheek portion can move towards each other about the axis when the mask body is held stationary and a force is exerted on the nose and chin portion (see **figures 6 and 7; inherently when the mask is used as shown in figure 7, the mask body will deform such that the first and second cheek portion can move towards each other**), and a harness 16 that assists in supporting the mask on a wearer's face (see **figures 6 and 7**).

6. **As to claim 2**, Nelson teaches an apparatus that further comprises one or more filter cartridges that are attached to the mask body (**see figure 1 and column 2 lines 50-60**).
7. **As to claim 3**, Nelson teaches an apparatus wherein the mask includes first and second filter cartridges that are secured to the first and second cheek portions, respectively (**see figure 1 and column 2 lines 50-60**).
8. **As to claim 5**, Nelson teaches an apparatus wherein the first and second cheek portions are capable of deflecting inward during normal jaw movement of the wearer (**see figures 6 and 7; inherently when the mask is used as shown in figure 7, the mask body will deform such that the first and second cheek portion can move towards each other**).
9. **As to claim 8**, Nelson teaches an apparatus wherein the mask body further includes a soft deformable material as a face seal, which soft deformable material is secured to a perimeter of the mask body to improve fit of the mask body to a person's face (**see column 3 lines 30-55**).
10. **As to claim 29**, Nelson teaches an apparatus wherein the mask body is constructed from a thermoformed plastic (**see column 2 lines 35-40**).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims **4, 6, 7, and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 4,960,121) in view of Brostrom et al. (US 6,062,221).

14. As to claims **4, 6 and 7**, Nelson substantially discloses the invention as claimed, see rejection of claim 1 above, but does not disclose a harness that includes a carriage and at least one strap, the carriage covering the exhalation valve and being secured to the mask body at the central portion. Brostrom discloses a drop-down facemask assembly that does provide a harness that includes a carriage **26 (see column 3 lines 50-60)** and at least one strap **44 and 46**, the carriage covering the exhalation valve (**see column 3 lines 50-60**) and being secured to the mask body at the central portion (**see figure 2**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Nelson's invention by providing a harness that includes a carriage and at least one strap, the carriage covering the exhalation valve and being secured to the mask body at the central portion as taught by Brostrom in order to provide an exhaust valve closer to the breathing passage of the user and so that the mask will not disengage from the carriage, nor from the user.

15. As to claim **18**, Nelson and Brostrom substantially discloses the claimed invention, see rejection of claims 1 and 6 above, but does not disclose a range of force that is used when the mask is fitted on a wearer's face. It would have been obvious to one having ordinary skill in the art at the time the invention was made to disclose a range of force that is used when the mask is fitted on a wearer's face, since it has

been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

16. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 4,960,121) in view of Brostrom et al. (US 6,062,221) and further in view of Springett et al. (US 5,617,849).

17. As to claim 9, Nelson and Brostrom substantially disclose the invention as claimed, see rejection of claim 1 above, but does not disclose a mask body that has a foam material secured to the interior of the mask body at the nose portion. Springett discloses an apparatus that does provide a mask body that has a foam material secured to the interior of the mask body at the nose portion (see column 5 lines 20-30). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Nelson and Brostrom inventions by providing a mask body that has a foam material secured to the interior of the mask body at the nose portion as taught by Springett in order to prevent contaminants from escaping to ambient.

18. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 4,960,121) in view of McCreadie et al. (US 4,579,113).

19. As to claim 10, Nelson substantially discloses the invention as claimed, see rejection of claim 1 above, but does not disclose a mask body having a mechanism that allows for attachment of a powered air supply source. McCreadie discloses an apparatus that does provide a mask body having a mechanism 62 that allows for attachment of a powered air supply source (see figure 5 and column 4 lines 1-10). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Nelson's invention by providing a mask body

having a mechanism that allows for attachment of a powered air supply source as taught by McCreadie in order to supply clean air in a contaminated environment.

20. Claims **11-17 and 19-28, 30, 31, 33 and -34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 4,960,121).

21. **As to claims 11-13**, Nelson substantially discloses the claimed invention, see rejection of claim 1 above, but does not disclose a numerical value of the elastic limit the mask body can elongate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a numerical value of the elastic limit the mask body can elongate, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F 2d 272, 205 USPQ 215 (CCPA 1980).

22. **As to claims 14-17**, Nelson substantially discloses the claimed invention, see rejection of claim 1 above, but does not disclose a numerical value for flexible modulus of the mask body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a numerical value for flexible modulus of the mask body, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F 2d 272, 205 USPQ 215 (CCPA 1980).

23. **As to claims 19 and 20**, Nelson substantially discloses the claimed invention, see rejection of claim 1 above, but does not disclose a numerical value of the deflection or a numerical value of the force required for the mask body deflection test. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a numerical value of the deflection or a numerical value of the force required for the mask body deflection test, since it has been held that discovering an optimum value of a result effective

variable involves only routine skill in the art. *In re Boesch*, 617 F 2d 272, 205 USPQ 215 (CCPA 1980).

24. As to claims 21-24, Nelson substantially discloses the claimed invention, see rejection of claim 1 above, but does not disclose a numerical value of the weight of the mask body in naked form. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a numerical value of the weight of the mask body in naked form, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F 2d 272, 205 USPQ 215 (CCPA 1980).

25. As to claims 25-28, Nelson substantially discloses the claimed invention, see rejection of claim 1 above, but does not disclose a numerical value of the thickness of the mask body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a numerical value of the thickness of the mask body, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F 2d 272, 205 USPQ 215 (CCPA 1980).

26. As to claims 31, 33 and 34, Nelson substantially discloses the claimed invention, see rejection of claim 1 above, but does not disclose a numerical value of the weight, thickness and flexural modulus of the mask body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a numerical value of the weight, thickness and flexural modulus of the mask body, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F 2d 272, 205 USPQ 215 (CCPA 1980).

27. As to claim 30, Nelson substantially discloses the claimed invention, see rejection of claim 1 above, but does not disclose a thermoformed plastic that comprises polypropylene. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a thermoformed plastic that comprises polypropylene, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 3772

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